REMARKS

1. Prior Art Issues

Claims 18-19, 22-23 and 40 are rejected as anticipated by Thiel, et al., Nature, 386:606 (1997).

The Examiner acknowledging that the Thiel reference was published on the same day (April 3, 1997) that the provisional application was filed. Hence, the reference is prior art only if the rejected claims are not entitled to the priority date of the provisional application. The Examiner so holds, characterizing the latter as a "verbatim copy" of the Nature publication.

We do not need to consider the "right of priority" issue (which we do not concede) because we can otherwise remove the Thiel reference as 102(a) prior art. Specifically, we can establish that it does not disclose the invention of "another" as required by 35 USC §102(a).

The inventors named in the present case are Jensenius and Thiel, both of whom are also co-authors of the reference. The "omitted" co-authors are Vorup-Jensen, Stover, Schwaeble, Laursen, Poulsen, Willis, Eggleton, Hansen, Holmskov and Reid.

All of the omitted co-authors save Stover have executed "disclaiming declarations", which are accepted under Ex parte Hirschler, 110 USPQ 384 (POBA 1952). Stover has refused to sign a disclaiming declaration.

The contributions of Stover have been carefully reviewed, see the enclosed Declaration of Jensenius executed October 18, 2003, and are not considered to be conceptual contributions which would warrant naming Stover as a joint inventor.

We recognize that when a coauthor refuses to sign a disclaiming declaration, a simple Katz-type declaration (In re Katz, 215 USPQ 14 (CCPA 1982)) to the effect that the coauthor worked "under the direction and supervision of the inventor" isn't enough to rebut the prima facie case. See Ex parte Kroger, 219 USPQ 370 (BPAI 1982). Kroger held that in such a situation, "further evidence" was necessary. Such evidence is provided by

the disclaiming declarations and by the Jensenius Declaration which details Stover's specific contributions.

The general legal standard is that "to be a joint inventor, an individual must make a contribution to the conception of the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention. Fina Oil & Chemical Co. v. Ewen 43 USPQ 2d 1935, 1941 (Fed. Cir. 1997).

This application is a division of 09/054,218 filed April 2, 1998. The parent application presented claims to MASP-2 polypeptides (1-11), a MASP-2 inhibitor (12), MASP-2 encoding nucleic acids (13-17), anti-(MASP-2) antibodies (18-21), pharmaceutical compositions (22), and various method claims (23-39); method claim 23, 24, and 26 recited use of a binding partner in an assay for MASP-2. By virtue of an amendment filed with this application, claims 1-17, 25, 27-36 and 38-39 were cancelled, and claim 22 amended to specify the presence of an antibody. Later, claim 37 was amended to require use of an antibody (October 25, 2002). Hence, the claims as presented for examination are essentially directed to antibodies, and methods for their use. Consequently, the inquiry as to inventorship must be similarly focused.

The "disclaiming" declarations were executed by Holmskov and Eggleton, in 1996; by Willis, Reid, Poulsen and Schwaeble in 1997, and by Vorup-Jensen, Hansen and Laursen in 2003.[1] The disclaiming declarations, in identical language, outline the work performed by Willis, Holmskov, Vorup-Jensen, Reid, Schwaeble and Stover. It is apparent that their contributions (conceptual or otherwise) were made only after anti-(MASP-2) antibodies were made and, indeed, after the antibody was used to immunoisolate the protein (which they credit to the named inventors, Thiel and Jensenius). None of them is said to have used the antibody in any way. Consequently, they cannot be deemed inventors with

[1] The signature on the Hansen declaration is difficult to read, but it was executed "19/9-2003".

respect to the present claims, which are directed to the antibodies and their use.

In the correspondence with Cordelia Stover (Ex. A), she did not dispute the factual accounting set forth in the disclaiming declaration. She only refused to concede that she was not an inventor.

Stover's contribution is addressed again in the rule 1.132 declaration executed by Dr. Jensenius on October 18, 2003. According to this declaration, her sole contribution related to the cloning and sequencing of MASP-2 cDNA, and anti-(MASP-2) antibodies had been made well before her entry into the project.

Since the disclaiming declarations and the October 18, 2003 Jensenius declaration related primarily to the characterization of the MASP-2 protein and the isolation and characterization of the MASP-2 gene, whereas the present claims are directed to the previously developed anti-(MASP-2) antibody, we submit new 1.132 declarations, executed by Thiel and Jensenius on October 27, which clarify that the antibody was prepared by Jensenius and Thiel.

Consequently, Stover and the other omitted co-authors cannot fairly be considered a joint inventor of the presently claimed antibodies and methods.

2. New Matter/Description/Enablement Issues

2.1. Technically speaking, a "new matter" rejection applies only to an amendment to the specification, while a "description" rejection applies to a comparable amendment to the claims.

2.2. The Examiner considers claim 40 to be to broad insofar as it generically recites an antigenic peptide of a length of 16 a.a. The examiner suggests limiting claim 40 to a "determinant containing fragment of SEQ ID NO:2". This suggestion has been followed.

2.3. The Examiner questions whether claim 42 contains "new matter" insofar as it covers antibodies against the serine protease domain. The Examiner assumes that we rely on the

teaching of inhibitory antibodies directed against the "active site of MASP-2" (page 42, line 6), and points out that the active site does not include the whole domain and that claim 42 does not require inhibitory activity.

However, on p. 31, l. 14-15 it is described that the antibodies according to the invention are raised to a MASP-2 polypeptide. A MASP-2 polypeptide may for example be a fragment comprising a biological function or activity of MASP-2 (p. 9, l. 3-6). The serine protease domain (described p. 48, l. 8) is a fragment comprising an activity, i.e. serine protease activity. We therefore respectfully request examiner to acknowledge support of claim 42 in the application as filed.

2.4. Claim 26 is rejected because examiner finds that assays for MASP-2 activity are not described in the application. However, on p. 39, l. 11 to p. 40, l. 11 a quantitative assay detecting the serine protease activity of MASP-2/MBL complexes is described and on p. 40, l. 13 to p. 41, l. 8 a quantitative assay for free MASP-2 serine protease activity is described. Both assays use complement factor 4 (C4) as substrate and cleavage of C4 by MASP-2 is determined. Hence, the description as filed indeed do enable a person skilled in the art to perform assays for MASP-2 activity.

3. Objections and Indefiniteness Issues

3.1. Claim 37 has been amended to indent each step of the method. We have also added a "correlating" step to better explain now the disorder is diagnosed.

3.2. In claim 18, "MASP-2 polypeptide" has been placed in parentheses, as suggested.

3.3. In claims 19 and 42, "selectively" has been replaced with --specifically--, as suggested.

3.4. In claim 23, we have amended step (b) to provide antecedent basis for "said complexes" in step (c).

Respectfully submitted,

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Enclosures
-disclaiming declarations of Vorup-Jensen, Schwaeble, Laursen, Poulsen, Willis, Eggleton, Hansen, Holmskov and Reid
-declaration of Jensenius (October 18, 2003)
-declarations of Jensenius and Thiel (October 27, 2003)
-Ex. A (extracts of correspondence between Stover and Jensenius re inventorship)

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